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(54) **Title:** BLOOD PUMP FOR THE INVASIVE APPLICATION WITHIN A BODY OF A PATIENT

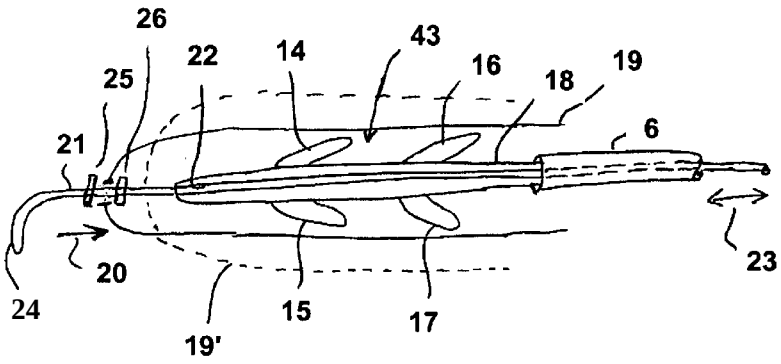

Fig. 2

(57) **Abstract:** The invention relates to a blood pump for the invasive application within a body of a patient comprising a rotor (43, 27) which is drivable about an axis of rotation and is radially compressible or expandable and which has a hub (18, 28) and at least one impeller blade (14, 15, 16, 17, 29, 30) fastened thereto, as well as comprising a housing (19, 19') which is compressible or expandable in the radial direction by an axial stretching or axial compression. The object of making both the rotor and the housing expandable and compressible in as simple a manner as possible is achieved in accordance with the invention in that a control body (21) is provided which passes through the hub (18) in the longitudinal direction, which is freely axially displaceable relative to the hub and which is coupled to the housing on the distal side of the rotor such that it exerts pulling and/or compression forces on the housing by a movement in the longitudinal direction with respect to the housing.

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Blood pump for the invasive application within a body of a patient

The invention is in the field of mechanical engineering, in particular micromechanics , and specifically relates to blood pumps.

US provisional application serial no. 61/364,559 (attorney's docket ECP 27(1) US), US provisional application serial no. 61/364,595 (attorney's docket ECP 27(2) US), and US provisional application serial no. 61/364,578 (attorney's docket ECP 28 US) are hereby incorporated by reference .

The use of the invention is in particular in the medical field where corresponding blood pumps have already become known in different designs for different purposes. Such pumps can be used invasively and can for this purpose be introduced via a blood

vessel into the body of a patient and can be operated there. Such pumps can be used particularly advantageously, for example, in a cardiac chamber, especially in a left ventricle, to assist the heart. Such a pump is for this purpose pushed in via a femoral artery by means of a hollow catheter and is introduced up to and into the left ventricle of a patient's heart. The blood pump there sucks in blood and expels it again in the aorta. In this manner, the heart's function can be replaced at least in part or can be assisted in order, for example, to relieve the heart in surgical procedures in this manner or to improve the conditions for a recovery of the patient's heart.

Such a pump has a drive which can, for example, be disposed outside the patient's body and the drive motion is transferred from said drive through the hollow catheter to the rotor by means of a rotatable shaft. However, the operation of microturbines in the proximity of the blood pump is also known for its drive .

A problem in the efficiency of such pumps is represented by the small dimensions which are advantageous for the transport within the patient's body. Such a pump or the rotor is usually radially compressible for the transport in order then to be expanded for the actual operation.

Various constructions have become known which allow a change of the rotor between a compressed state and an expanded state. Constructions are, for example, known having support struts made from memory alloys which change their shape in dependence on the environmental temperature . The support structures can then be

spanned by a membrane to form the impeller blades of a rotor.

Single-part rotors with hubs are also known to which impeller blades are fastened in one piece which can be folded onto the hub and spread apart from it due to their balanced elastic properties. The compression of the impeller blades often takes place by the housing which surrounds the rotor and can be enlarged for the expansion. The erection of the impeller blades can take place, for example, by the rotation of the rotor in operation in that the impeller blades are erected by the arising fluid counter-pressure on the rotation.

A problem in the construction of such blood pumps is, for example, that the demands on the material properties of the material from which the rotor or especially the impeller blades are made are very high. The impeller blades have to be deformed a great deal in locally bounded regions for the complete folding onto the hub, and it is also desirable that the compression forces required for the compression remain small to be able to compress the rotor without any great effort and without any excessive wear. Composite materials have been proposed for this purpose for manufacturing the impeller blades.

On the one hand, they provide an impeller blade body made from a relatively elastic material and on the other hand additional struts which can be integrated into an impeller blade body or which can be placed onto it and which stabilize and support the impeller blade at least in the expanded state.

Various proposals have already become known for a sensible expansion of both the rotor and of the housing surrounding it, such as, for example, the proposal also to expand the housing by the expansion of the rotor or to expand the housing independently of the rotor and thereby to allow the elastic forces acting in the rotor to work which at least partly expand the impeller blades automatically.

Corresponding constructions have become known, for example, from WO 03/103745 and WO 94/05347. It is also proposed there, for example, to apply longitudinal forces to the housing in order to compress it axially, for example, as part of a puling movement, and thus to expand it radially.

It is the underlying object of the present invention to design a blood pump of the initially named kind on the basis of the background of the prior art such that a good compression, as free of forces as possible, of a rotor and/or of the housing of a blood pump is made possible with a construction effort which is as small as possible, with the rotor being stabilized as much as possible in the desired geometrical shape in the expanded state.

The object is satisfied by the features of the independent claims.

A blood pump is accordingly provided for the realization of the invention which has a rotor which can be driven about its axis of rotation and is radially compressible and expandable to be transported through the blood vessel in the compressed state.

In addition, the rotor has a hub and at least one impeller blade fastened thereto and a housing which can be compressed or expanded in the radial direction by an axial stretching or axial compression.

A control body is moreover provided which passes through the hub in the longitudinal direction and which is coupled to the housing on the distal side of the rotor such that it exerts pulling forces and/or compression forces on the housing by a movement in the longitudinal direction with respect to said housing. The control body can preferably be axially displaceable relative to the hub.

Although it is generally known to compress and/or expand corresponding pump housings by exertion of axial forces, no movement or force transmission by the rotor or by the hub itself is required for this purpose with the present invention. An actuation by a control body which passes through the hub can rather take place . Said control body can either rotate with the rotor or be rotationally stationary with respect to it. The control body can, for example, be a guide wire which is introduced into a patient's body before the pump and via which the pump can be pushed to the deployment site.

The control body is freely displaceable in the hub, that is with respect to all parts of the hub. This means that no interaction with the hub occurs on an axial displacement. The pump housing is axially compressed or stretched and thus radially expanded or compressed by actuation of the control body. The rotor has conveying elements which advantageously project radially from the hub and which are radially elastically compressible and are ideally

automatically erected on the radial expansion of the housing, in particular exclusively by elastic forces.

The control body can, for example, extend in a hollow drive shaft which is coupled to the hub of the rotor and advantageously also fixes it in the axial direction .

The rotor can also be pushed into the housing in the distal direction after the expansion of the pump housing independently of the control body in the axial direction.

The conveying elements, preferably in the form of conveying blades, are preferably shaped so that they are erected further radially from a position unfolded in a force-free manner in operation to adopt the ideal hemodynamic shape in this position. On a longitudinal stretching of the housing and a corresponding radial compression, the conveying elements can hereby also be compressed.

The control body can be axially displaceably connected to the housing, in particular to its distal end, at the join position. In this respect, the control body can be rotatably supported in the hosing wall .

Provision can advantageously be made that the control body has an abutment body on the distal side of the housing wall, with said abutment body exerting an axial compression force onto the housing wall and thus radially expanding the housing on a pulling movement in the proximal direction.

Provision can additionally or alternatively also be made for this purpose that the control body has an abutment body on the proximal side of the housing wall, with said abutment body exerting an axial expansion force onto the housing wall on a pushing movement in the distal direction.

The corresponding abutment bodies should merely be larger than the bore in the housing wall which passes through the control body. The abutment bodies can also be fastened to the guide body such that they are displaceable lengthways on the control body on application of a specific minimum force. Too great a compression or expansion of the housing is thereby prevented.

Provision can also be made that the abutment bodies can be pressed through the bore in the wall of the pump housing on the exceeding of a specific force threshold, for example when the guide body should be finally removed. Provision can, for example, be made for this purpose that the abutment bodies comprise a compressible material such as foam.

Provision can also be made that the abutment body arranged distal or proximal to the housing wall is dissoluble or deformation such that the control body can be removed. This embodiment can also allow the final removal of the guide body despite the abutment bodies.

The housing of the pump can advantageously have a movable grid mesh simultaneously to produce an expansion or compression in the radial direction by a compression or expansion in the longitudinal direction .

The grid can, for example, have a structure of grid bars which are arranged at least partly helically about the axis of rotation.

The housing can have a membrane supported by the grid mesh for the sealing of said housing. The membrane can be molded with the grid mesh. The grid mesh can also be molded around by an injection molding material.

A further embodiment of the invention relates in accordance with claim 7 to a blood pump for the invasive application within the body of a patient having a housing and a rotor which is arranged in said housing in operation, which is drivable about an axis of rotation and has at least one impeller blade, with the rotor and/or the housing being radially compressible and expandable, characterized in that the rotor and/or the housing at least partly comprises a material which is modified in selected regions with respect to other regions such that it differs from the other regions in the selected regions with respect to at least one mechanical material property such as Young's modulus, the yield strength, the brittleness, elastic stretchability, hardness and/or toughness and/or the Shore hardness.

The selected regions in this respect preferably each extend on only one side of the axis of rotation between a first radial spacing (larger than zero) from the axis of rotation and a larger second radial spacing from the axis of rotation. The first radial spacing is advantageously larger than the radius of the hub if the rotor has a hub. The selected regions

thus do not extend radially inwardly up to the axis of rotation or not even up to the hub.

The selected regions can furthermore be free, i.e. not connected to one another, in their parts disposed radially furthest inwardly with respect to the axis of rotation, i.e. close to the axis. This embodiment allows an extremely large freedom of design and permits very large and very free deformations of the rotor, with such designs practically not being able to be manufactured with the aid of prefabricated structures in the form of connected struts or being so unstable that they show unpermitted deformation on the insertion molding, insertion injection or other molding processes. Such selected regions, which are unstable per se, can be introduced into the molded rotor, which serves as a carrier of the selected regions, by the creation and design of the selected regions during or after the molding process.

The selected regions can in extreme cases also all be provided without any mutual connection. The conveying blades can moreover be manufactured with a constant wall thickness since no separate struts have to be insertion molded.

An advantageous embodiment of the invention provides that the selected regions may differ from the other regions by a physical and/or chemical structure. In this respect, the selected regions can differ from the other regions, for example, with respect to their crystalline structure modification, density, the degree of foaming or the chemical cross-linking or other conceivable physical or chemical ordering forces on a molecular or atomic level; the regions

can, however, also comprise the same base material in this respect.

The rotor and/or the housing preferably at least partly comprise a material which is modified in selected regions with respect to other regions of the same material with respect to at least one mechanical property. Instead of a modification of the same material, a new material can also arise in the selected regions which, however, belongs to the same class as the starting material. Such classes of materials can be modifications of metals, plastics or kinds of plastic, for example.

The rotor or parts of the rotor are usually first molded in a molding process such as casting, injection, pressing or extrusion. It can then be shaped, bent, stretched, compressed or otherwise treated; it at least has a fixed shape, that is, is solidified, after the shaping.

Provision can be made that the selected regions are modified during the molding process or that the selected regions are modified after the molding process or also that the regions are modified after a first molding process by an additional shaping process .

It can be particularly advantageous in this respect if at least one part of the rotor, in particular an impeller blade, and/or at least one part of the housing comprises a material which can be softened or hardened by radiation and if selected regions are stiffened by selective radiation hardening or if correspondingly selected regions are softened by selective radiation softening. It is generally

conceivable in this respect that the material in the selected regions can be modified by radiation, in particular by alpha radiation, beta radiation or gamma radiation and/or by thermal radiation. Mechanical support structures in the form of selected regions can be inscribed into the material of the rotor and/or of the housing in this manner by means of focusable radiation.

The selected regions can already be produced by special casting processes, injection molding processes or extrusion processes in molding processing during shaping. Application processes or immersion processes are also conceivable in which layer grows on layer and in so doing, for example, substance concentrations, solvent concentrations or composition ratios are changed, for example. It is also possible to produce these structures by drop-wise application of the material, with the composition being able to be varied drop-wise.

The selected regions can, however, also only be correspondingly treated after the shaping process, i.e. when the rotor has its final later shape, to change the material directly.

The impeller blade or blades substantially comprise(s) a deformable material, in particular an elastic material, which is easily deformable for the compression of the rotor. High demands on the mechanical stability are, however, made thereon in the elongated position in rotation/pump operation. These demands can be satisfied by a combination of different materials such as a yielding, flexible material and a strut of a harder material as a composite component.

A particularly simple embodiment of such a composite component is provided by the invention in that the impeller blade body comprises a material hardenable or softenable by radiation and selected regions of the impeller blade are selectively hardened as supporting structures or other regions are softened.

Corresponding radiation sources can be sufficiently focused to treat the regions to be hardened accordingly in a selective and delineable manner.

The supporting structures / selected regions are advantageously made as struts which extend within the impeller blade from a point close to the axis of rotation to a point remote from the axis of rotation.

The struts can extend directly in the radial direction or also be inclined at an angle toward the longitudinal axis of the rotor. They can extend from the hub up to the outer end of the impeller blade or over a part distance of this spacing. A meandering or zig-zag extent of the struts is also possible which support the compression of the rotor by forming suitable bending zones .

Such regions formed as struts can, for example, be formed in the housing in the peripheral direction, in the longitudinal direction parallel to the axis of rotation or also running helically about the axis of rotation.

Different struts can be designed parallel to one another, but also in beam form running apart from one another. The force lines of the forces acting under load in an impeller blade can be modeled by the

struts. In this case, a plurality of struts can run apart from one another in beam form, for example, from one point or one region.

Provision can also advantageously be made that transition regions which have a smaller degree of hardness than the hardened structures and a higher degree of hardening than the non-hardened regions are provided between the hardened support structures and the non-hardened regions of the impeller blade or of the housing.

The hardening of the support structures subsequently after manufacture of the impeller blade body or of the housing provides the possibility of producing a gradual material transition between a yielding material and a hardened material within the impeller blade body.

The hardened regions can, for example, be arranged at the surface and also only be arranged at the surface of the impeller blade or of the housing or they can lie deep in the interior of the impeller blade or of the housing.

Whole part surfaces within the impeller blades or housing can also be hardened as supporting structures, such as circular or oval plates which can have an extremely stable shape of a spherical cap as required, for example.

The invention also relates, in addition to a blood pump of the above-named kind having the stated advantageous further developments, to a method of manufacturing a blood pump in which the rotor, in particular an impeller blade and/or the housing, is

manufactured inhomogeneously in shaping by means of a injection process, an injection molding process or an extrusion process or an application process and/or is modified with respect to mechanical material properties after shaping by radiation in selected regions .

The invention will be shown and subsequently described in the following with reference to an embodiment in a drawing. There are shown

Fig. 1 schematically, in an overview, a heart catheter pump which is inserted at least partly into a ventricle;

Fig. 2 in a longitudinal section, the structure of a pump with a rotor and a housing;

Fig. 3 the housing of a pump;

Fig. 4 in a three-dimensional view, a rotor of a pump with a hub;

Fig. 5 in a three-dimensional view, a hubless rotor;

Fig. 6 a detail from a longitudinal section through a pump housing; and

Fig. 7 a housing of a pump reinforced by different types of struts.

Fig. 1 shows a pump 1 which projects into a ventricle 2 of a human heart which is only shown schematically. The pump 1 has a suction cage 3 which leaves openings

free for sucking in blood. The inflowing blood is symbolized by the arrows 4, 5.

A rotor is provided within the pump 1, said rotor rotating at a speed between 3000 and 50,000 r.p.m. and conveying the blood into the blood vessel 13 in the longitudinal direction. For this purpose, an outflow hose is pushed over the pump which has outflow openings 10 proximal to the heart valve through which the blood flows off in the direction of the arrows 11. The pump 1 is held at the end of a hollow catheter 6 which is introduced through a sluice 8 into the body of a patient and is there directly introduced into a blood vessel 13. A drive shaft 7 is guided within the hollow catheter 6 and is connected outside the body to a motor 9 and in the pump 1 to a rotor.

Fig. 2 shows the inner structure of the pump 1 in a more detailed representation. A housing 19 is shown in whose interior a rotor 43 is arranged. The rotor 43 has a central hub 18 to which impeller blades 14, 15, 16, 17 are fastened.

To make the rotor radially compressible and expandable, the impeller blades 14, 15, 16, 17 can be laid radially onto the hub 18 to reduce the radius of the pump. The housing 19 is also compressed in its radius in this state.

The impeller blades as well as optionally the hub 18 advantageously comprise an elastic, yielding material which can, however, be reinforced by struts or supports so that the impeller blades can be folded tightly onto the hub due to the yielding, on the one

hand, but can remain erected up to the full radial extent, on the other hand.

The impeller blades 14, 15, 16, 17 are usually erected up to and into the expanded state by the putting into operation of the rotor on rotation as a consequence of the fluid counter-pressure which occurs and/or as a consequence of the centrifugal forces. Alternatively to this, or additionally, struts or a framework of a memory material such as nitinol can also be provided which erect the impeller blades on the transition into the expanded state. The housing 19 can also be expanded into the shape 19' shown in Fig. 2 by dashed lines due to this during the erection of the impeller blades.

To facilitate this procedure and to utilize another mechanism for the radial expansion of the housing 19, a control body 21 is provided in accordance with the invention which is formed as a guide wire in the example shown, which passes centrally through an opening 22 in the hub 18 and projects through the wall of the housing 19 to distal at its distal end.

The control body projects through the hub 18 and the hollow catheter 6 and can be actuated, i.e. can be displaced in the longitudinal direction, from outside the body. The control body has a first abutment body 25 distal from the wall of the housing 19 and a second control body 26 proximal to the wall of the housing 19, with the abutment bodies 25, 26 having an at least partially larger radial extent than the opening in the housing 19 which is passed through.

If the control body 21 is retracted in the direction of the arrow 20, that is, in the proximal direction,

the housing 19 is thus pressurized in the axial direction and pushed together. Since the housing 19 comprises a movable mesh, for example a wire mesh or a mesh of fibers with a partially helical extent, it is automatically radially expanded on such an axial compression.

The housing is thus moved into the expanded form in which it provides sufficient space for the rotation for the expanded impeller blades.

Fluid can thus accordingly be conveyed within the housing in the axial direction by the impeller blades 14, 15, 16, 17.

The abutment body 25 can be designed such that it first effects an axial compression of the housing 19 on a retraction in the direction of the arrow 42 in Fig. 6, but, on a subsequent larger application of force, is pulled into the recess 41 of the housing 19 due to the conical shape and can be pulled through the opening 41 on a further increase in the axial force. This can be assisted in that the body 25 comprises an at least partially yielding material, for example a foam.

The abutment bodies can also comprise a material, for example, which dissolves in bodily fluids, in particular blood, over time so that the control body can be removed without problems after it has satisfied its function of compression or expansion of the housing 19.

The second abutment body 26 can be utilized corresponding to the abutment body 25 for an axial expansion of the housing 19 in that the control body

21 is pushed in the opposite direction to the arrow 20 in Fig. 2 and thus an axial expansion force is exerted onto the housing. Within the course of this axial expansion, the housing 19 simultaneously undergoes a radial compression, in the course of which a radial compressive force is also exerted onto the impeller blades 14, 15, 16, 17 so that they are additionally compressed.

In the example shown, the rotor 18 can rotate freely relative to the control body 21 so that the control body 21 is made fixed relative to the rotor with respect to the rotation.

The control body 21 can alternatively to the example shown in the Figures also serve the rotational journalling of the rotor 43 at the distal end of the housing 19.

For this purpose, the control body 21 can be non-displaceably connected to the housing 19 and can be journalled in an axially fixed bearing at the housing 19. On the other hand, the rotor, in particular the hub 18, can also be journalled with respect to the control body 21 by a roller element bearing or plain bearing arranged between them.

Fig. 4 shows in a three-dimensional view a rotor 27 of a compressible and expandable blood pump with a hub 28 which carries two impeller blades 29, 30. The impeller blades 29, 30 run helically about the hub 28. The impeller blades and the hub can, for example, comprise the same flexible, in particular elastic, material .

The impeller blades can also be made shorter than shown in the illustration so that a plurality of impeller blades are distributed at the periphery of the hub 28.

Supporting structures 32, 33, 34 in the form of integrated struts which are arranged within the volume of the impeller blade 29 are shown within the impeller blade 29. They are formed in accordance with the invention in that specific regions within the material or a material of the impeller blade 29 are hardened directly and selectively.

For this purpose, the impeller blade 29 at least partially comprises a material which can be hardened by means of radiation, in particular light, UV light, laser radiation, X-rays or alpha radiation, beta radiation or gamma radiation, for example an elastomer having hardenable portions. It can in this respect be a radiation-cross linkable rubber, for example .

A controllable laser 31 is shown by way of example in Fig. 4 by means of which the regions of the support structures can be radiated directly and thus be hardened to the desired degree. The contours of the regions to be hardened can thus be designed as sharp; it is, however, also conceivable to provide gradual transitions between hardened regions and non-hardened regions in which the material is only partially hardened .

The struts can advantageously be arranged in the expanded state in the radial direction of the rotor. The formation of the struts by the radiation hardening can advantageously take place in the force-

free state or in the expanded state to achieve the desired shape and alignment of the supporting structures as precisely as possible.

Fig. 5 shows a hubless rotor having an impeller blade 35 into which support structures 36, 37, 38, 39, 40 in the form of struts extending in beam shape are introduced by selective solidification.

Fig. 7 shows selected hardened regions at a housing 50 for the example of struts 51 extending parallel to the axis of rotation, struts 52 extending in the peripheral direction and struts 53 running around helically.

The formation of the support structures by means of a controllable irradiation also has the advantage with respect to the introduction of prefabricated fixed structures that very complex geometrical forms can be produced as support structures. In addition, an insertion molding of struts using an injection molding material, with the struts being able to be deformed or displaced by the application of force in dependence on the viscosity of the injection molding material, is dispensed with.

Thanks to the design of various elements of the pump, the invention allows a comfortable compression or expansion of the pump, together with an optimized stability in the expanded state and a good and reversible compressibility of the impeller blades.

Aspects of the invention are inter alia:

1. A blood pump for the invasive application within a body of a patient comprising a rotor (43, 27) which is drivable about an axis of rotation, which is radially compressible and expandable and which has a hub (18, 28) and at least one impeller blade (14, 15, 16, 17, 29, 30) fastened thereto as well as comprising a housing (19, 19') which is compressible or expandable in the radial direction by a axial stretching or axial compression, characterized in that a control body (21) passing through the hub (18) in the longitudinal direction is provided which is coupled to the housing on the distal side of the rotor such that it exerts pulling and/or compression forces onto the housing by a movement in the longitudinal direction with respect to the housing.

2. A blood pump in accordance with aspect 1, characterized in that the control body (21) rotates with the rotor (18).

3. A blood pump in accordance with aspect 1, characterized in that the control body (21) is stationary with respect to the rotor (18).

4. A blood pump in accordance with aspect 1 or one of the following aspects, characterized in that the control body (21) is axially non-displaceably connected to the housing (19, 19').

5. A blood pump in accordance with aspect 1, aspect 2 or aspect 3, characterized in that the control body (21) passes through the housing wall and has at its distal side an abutment body (25)

which exerts a compressive force in the axial direction onto the housing on the retraction of the control body in the proximal direction.

6. A blood pump in accordance with one of the aspects 1, 2, 3 or 5, characterized in that the control body (21) has an abutment body (26) on the proximal side of the housing wall, said abutment body exerting an axial expansion force onto the housing wall on a pushing movement in the distal direction.

7. A blood pump in accordance with aspect 1 or one of the following aspects, characterized in that the control body (21) is made as a guide wire.

8. A blood pump in accordance with aspect 1 or one of the following aspects, characterized in that the abutment body (25, 26) arranged distal or proximal to the housing wall can be dissolved or deformed such that the control body can be removed .

9. A blood pump in accordance with aspect 1 or one of the following aspects, characterized in that the housing (19, 19') has a movable grid mesh.

10. A blood pump in accordance with aspect 9, characterized in that the housing (19, 19') has a membrane supported by the grid mesh.

11. A blood pump for the invasive application within the body of a patient comprising a housing as well as a rotor (43, 27) which is arranged in said housing in operation and has at least one impeller blade (14, 15, 16, 17, 29, 30, 35), wherein the rotor and/or the housing (19, 19') is/are radially compressible and expandable,

characterized in that the rotor and/or the housing comprise(s) at least partially a material which is modified in selected regions (32, 33, 34, 36, 37, 38, 39, 40) with respect to other regions such that it differs from the other regions with respect to mechanical properties in the selected regions.

12. A blood pump in accordance with aspect 11, characterized in that the selected regions (32, 33, 34, 36, 37, 38, 39, 40) differ from the other regions by a physical and/or chemical structure .

13. A blood pump in accordance with aspect 11 or aspect 12, characterized in that the selected regions (32, 33, 34, 36, 37, 38, 39, 40) are modified during the molding process.

14. A blood pump in accordance with aspect 11 or aspect 12, characterized in that the selected regions (32, 33, 34, 36, 37, 38, 39, 40) are modified after the shaping process.

15. A blood pump in accordance with aspect 11 or one of the following aspects, characterized in that at least a part of the rotor (43, 27), in particular an impeller blade, and/or at least a part of the housing comprise(s) a material which be softened or hardened by radiation; and in that selected regions (32, 33, 34, 36, 37, 38, 39, 40) are stiffened by selective radiation hardening or correspondingly selected regions are softened by selective radiation softening.

16. A blood pump in accordance with aspect 11 or one of the following aspects, characterized in that the material is modified in the selected regions

by radiation, in particular by alpha radiation, beta radiation or gamma radiation and/or by thermal radiation.

17. A blood pump in accordance with aspect, 11, aspect 12 or aspect 13, characterized in that stiffened selected regions (32, 33, 34, 36, 37, 38, 39, 40) are struts which extend within the impeller blade (29, 30, 35) from a point close to the axis of rotation to a point remote from the axis of rotation.

18. A blood pump in accordance with aspect 11 or one of the following aspects, characterized in that transition regions which have a lower degree of hardness than the hardened structures and a higher degree of hardness than the non-hardened regions are provided between the hardened support structures (32, 33, 34, 36, 37, 38, 39, 40) and the non-hardened regions of the impeller blade (29, 30, 35) or of the housing.

19. A blood pump in accordance with aspect 11 or one of the following aspects, characterized in that the selected regions, in particular supporting structures, are disposed at the surface of the impeller blade (29, 30, 35) or of the housing.

20. A blood pump in accordance with aspect 11 or one of the following aspects, characterized in that the supporting structures are disposed in the interior of the impeller blade (29, 30, 35) .

21. A method of manufacturing a blood pump in accordance with one of the aspects 11 to 20, characterized in that the rotor (43, 27), in particular an impeller blade (14, 15, 16, 17, 29, 30, 35), and/or the housing (19, 19') is/are

manufactured inhomogeneously by means of an injection process, an injection molding process or an extrusion process or an application process on the shaping and/or is/are modified with respect to mechanical material properties after the shaping by radiation in selected regions (32, 33, 34, 36, 37, 38, 39, 40) .

22. A method in accordance with aspect 21, wherein the injection process is characterized by drop-wise application of the material with variation of the composition of the drops.

ECP Entwicklungsgesellschaf t mbH
117PCT 0831 / ECP 27(2) PCT

Claims

1. A blood pump for the invasive application within a body of a patient comprising a rotor (43, 27) which is drivable about an axis of rotation, which is radially compressible and expandable and which has a hub (18, 28) and at least one impeller blade (14, 15, 16, 17, 29, 30) fastened thereto as well as comprising a housing (19, 19') which is compressible or expandable in the radial direction by a axial stretching or axial compression, characterized in that a control body (21) passing through the hub (18) in the longitudinal direction is provided which is coupled to the housing on the distal side of the rotor such that it exerts pulling and/or compression forces onto the housing by a movement in the longitudinal direction with respect to the housing.

2. A blood pump in accordance with claim 1, characterized in that the control body (21) rotates with the rotor (18);
or in that the control body (21) is stationary with respect to the rotor (18);
and/or in that the control body (21) is axially non-displaceably connected to the housing (19, 19').

3. A blood pump in accordance with claim 1 or claim 2, characterized in that the control body (21) passes through the housing wall and has at its

distal side an abutment body (25) which exerts a compressive force in the axial direction onto the housing on the retraction of the control body in the proximal direction;

and/or in that the control body (21) has an abutment body (26) on the proximal side to the housing wall, said abutment body exerting an axial expansion force onto the housing wall on a pushing movement in the distal direction.

4. A blood pump in accordance with claim 1, claim 2 or claim 3, characterized in that the control body (21) is made as a guide wire.

5. A blood pump in accordance with claim 1, claim 2, claim 3 or claim 4, characterized in that the abutment body (25, 26) arranged distal or proximal to the housing wall is dissolvable or deformable such that the control body can be removed.

6. A blood pump in accordance with claim 1, claim 2, claim 3, claim 4 or claim 5, characterized in that the housing (19, 19') has a movable grid mesh;

and/or in that the housing (19, 19') has a membrane supported by the grid mesh.

7. A blood pump for the invasive application within the body of a patient comprising a housing as well as a rotor (43, 27) which is arranged in said housing in operation and has at least one impeller blade (14, 15, 16, 17, 29, 30, 35), wherein the rotor and/or the housing (19, 19') is/are radially compressible and expandable, characterized in that the rotor and/or the housing comprise(s) at least partially a

material which is modified in selected regions (32, 33, 34, 36, 37, 38, 39, 40) with respect to other regions such that it differs from the other regions with respect to mechanical properties in the selected regions.

8. A blood pump in accordance with claim 7, characterized in that the selected regions (32, 33, 34, 36, 37, 38, 39, 40) differ from the other regions by a physical and/or chemical structure and/or are each only disposed on one side of the axis of rotation between a first radial spacing from the axis of rotation and larger second spacing from the axis of rotation.

9. A blood pump in accordance with claim 7 or claim 8, characterized in that the rotor is shaped at least partially by a molding process from a liquid, injectable or loose-fill substance; and in that the selected regions (32, 33, 34, 36, 37, 38, 39, 40) are modified during the molding process ;

or in that the selected regions (32, 33, 34, 36,. 37, 38, 39, 40) are modified after the molding process .

10. A blood pump in accordance with claim 7, claim 8 or claim 9, characterized in that at least a part of the rotor (43, 27), in particular an impeller blade, and/or at least a part of the housing comprise (s) a material which be softened or hardened by radiation; and in that selected regions (32, 33, 34, 36, 37, 38, 39, 40)) are stiffened by selective radiation hardening or correspondingly selected regions are softened by selective radiation softening.

11. A blood pump in accordance with claim 7, claim 8 or claim 9, characterized in that selected regions (32, 33, 34, 36, 37, 38, 39, 40) are stiffened for forming struts which extend within the impeller blade (29, 30, 35) from a point close to the axis of rotation to a point remote from the axis of rotation.

12. A blood pump in accordance with claim 7, claim 8, claim 9, claim 10 or claim 11, characterized in that selected regions are hardened to form support structures; and in that transition regions which have a lower degree of hardness than the hardened structures and a higher degree of hardness than the non-hardened regions are provided between the hardened structures (32, 33, 34, 36, 37, 38, 39, 40) and the non-hardened regions of the impeller blade (29, 30, 35) or of the housing.

13. A blood pump in accordance with claim 7, claim 8, claim 9, claim 10, claim 11 or claim 12, characterized in that the selected regions, in particular supporting structures, are disposed at the surface of the impeller blade (29, 30, 35) or of the housing;
and/or in that the supporting structures are disposed in the interior of the impeller blade (29, 30, 35).

14. A method of manufacturing a blood pump in accordance with one of the claims 7 to 13, characterized in that the rotor (43, 27), in particular an impeller blade (14, 15, 16, 17, 29, 30, 35), and/or the housing (19, 19') is/are manufactured inhomogeneously by means of an

injection process, an injection molding process or an extrusion process or an application process on the shaping and/or is/are modified with respect to mechanical material properties after the shaping by radiation in selected regions (32, 33, 34, 36, 37, 38, 39, 40) .

15. A method in accordance with claim 14, wherein the injection process is characterized by drop-wise application of the material with variation of the composition of the drops.

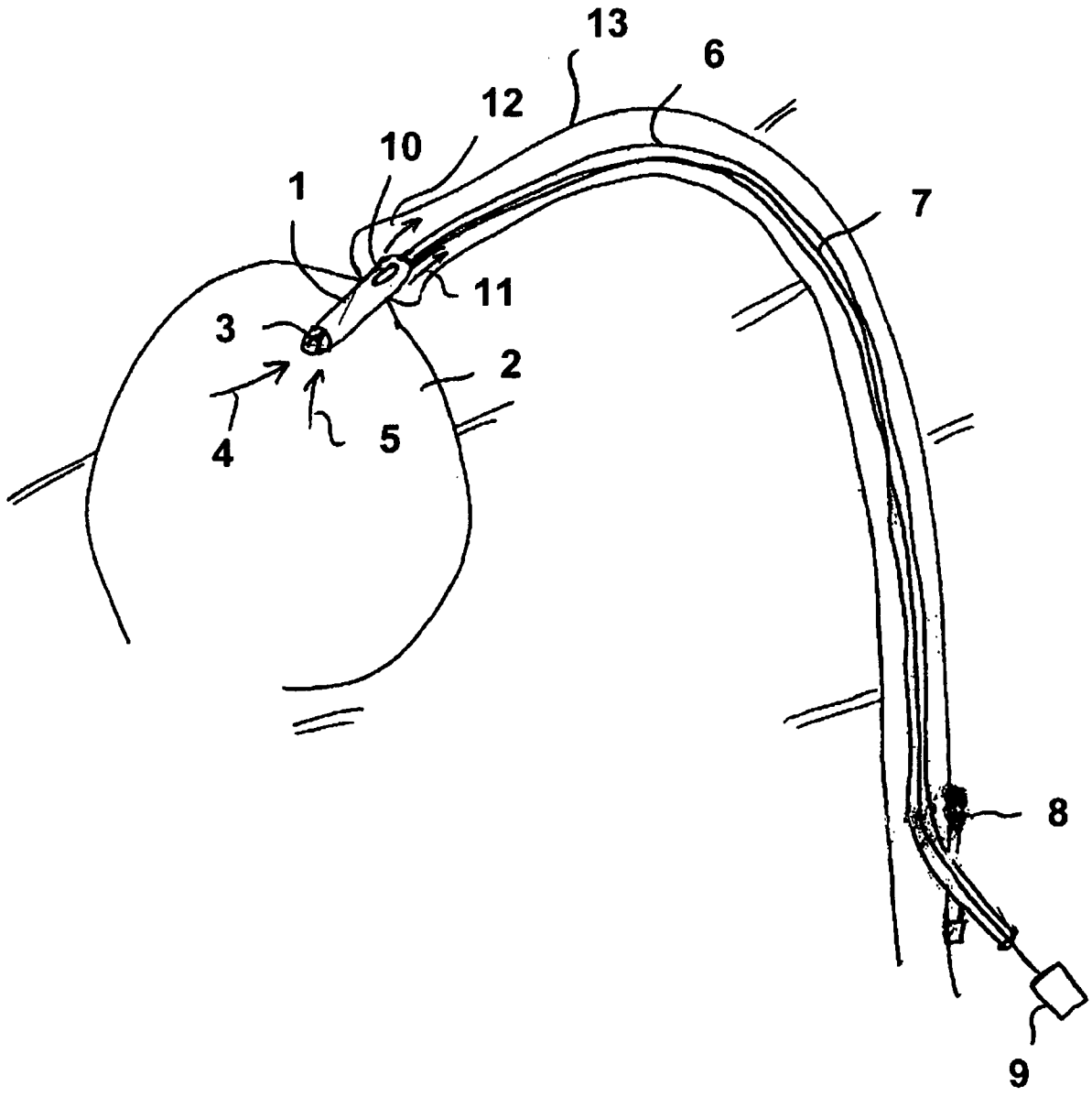

Fig. 1

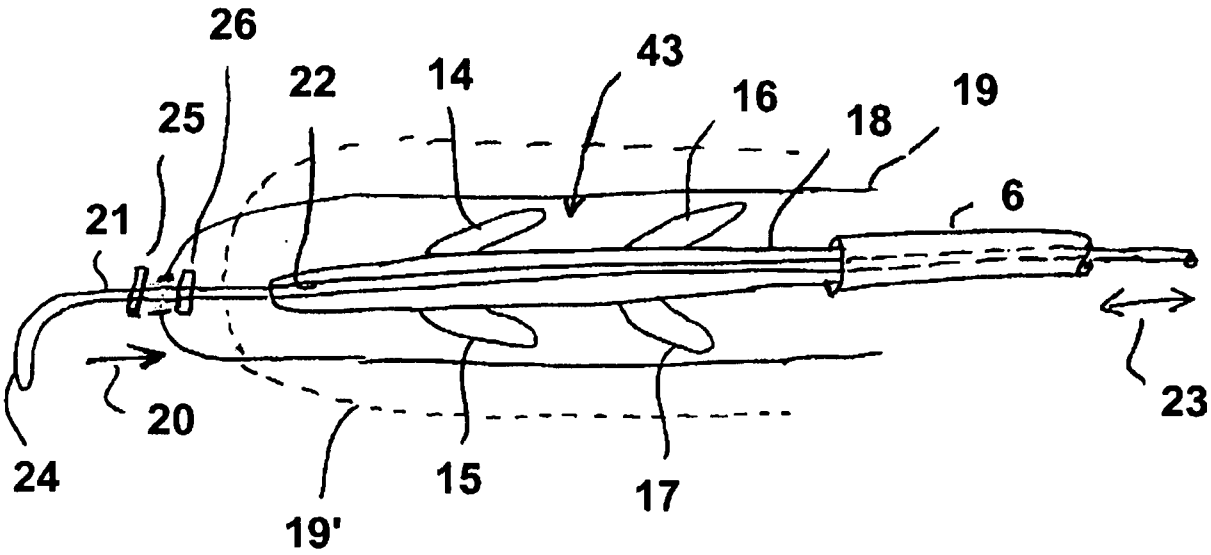

Fig. 2

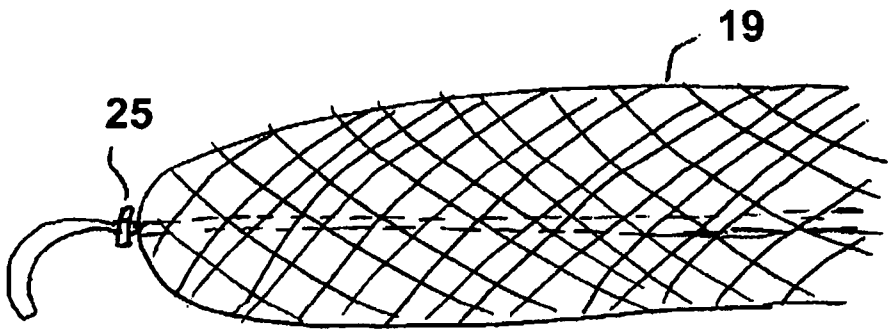

Fig. 3

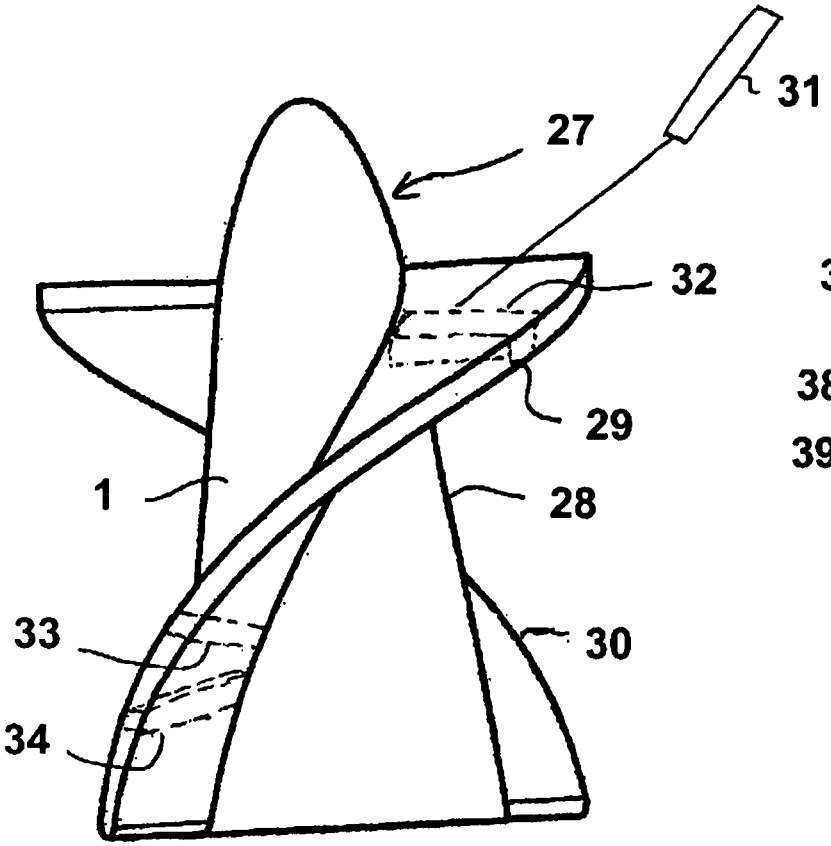

Fig. 4

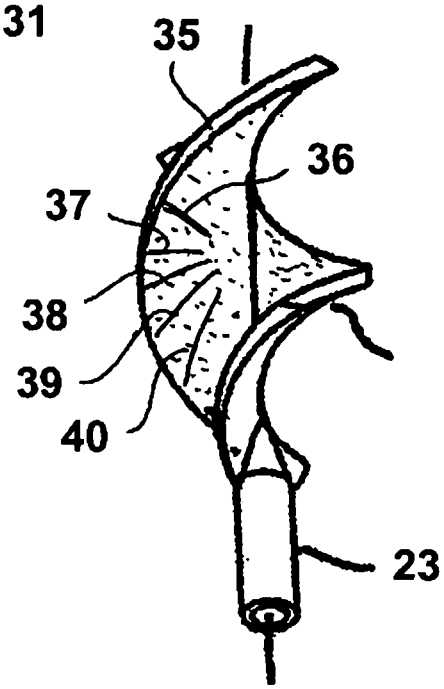

Fig. 5

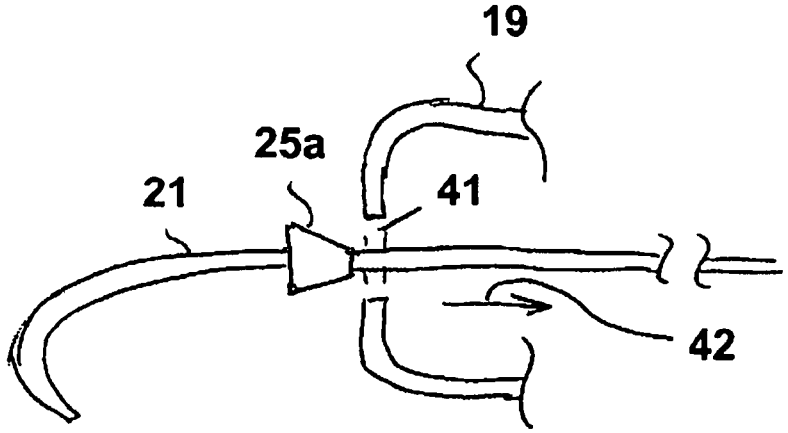

Fig. 6

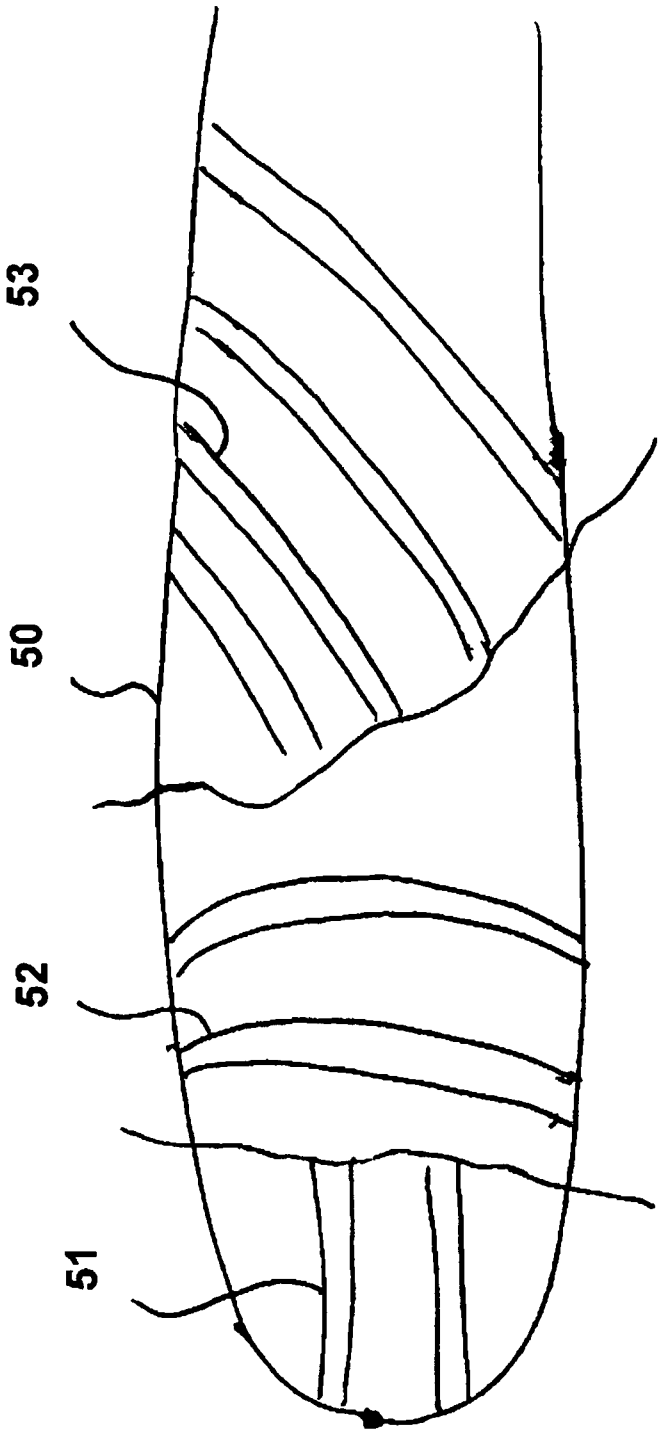

Fig. 7

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2011/003438

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M1/10 A61M1/12
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M B29C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 03/103745 A2 (AB0UL-H0SN WALID [US]) 18 December 2003 (2003-12-18) page 17; figure 14	1

A	WO 94/05347 Al (REITAN 0EYVIND [SE]) 17 March 1994 (1994-03-17) page 8 - page 9 figures 9, 10	1-3, 6

X	WO 2010/042546 Al (UNIV INDIANA RES & TECH CORP [US] ; R0DEFELD MARK D [US] ; FRANKEL STEVE) 15 April 2010 (2010-04-15)	14
A	page 34 - page 35 figures 10, 11	3, 15

	-/- ·	

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" documentwhich may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such docu¬ments, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
7 September 2011	15/09/2011

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Bi chlmayer, K

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Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 100 59 714 CI (IMPELLA CARDIOTECH AG [DE]) 8 May 2002 (2002-05-08) paragraph [0003] - paragraph [0010] paragraph [0027] - paragraph [0031] figures 6,7,12	1,4-6
X	US 2009/093796 Al (PFEFFER JOACHIM GEORG [DE] ET AL) 9 April 2009 (2009-04-09)	7-11,13
A	paragraph [0106] - paragraph [0107] ; figures 2,68,12,13 paragraphs [0069] - [0073] paragraphs [0087] - [0093]	1,6
A	US 6 193 922 Bl (EDERER ING0 [DE]) 27 February 2001 (2001-02-27) column 3, lines 31-56	14,15
A	DE 10 2006 031273 Al (DAIMLER CHRYSLER AG [DE]) 10 January 2008 (2008-01-10) paragraphs [0005] , [0016]	14

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2011/003438

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 03103745 A2	18-12-2003	AU 2003236497 A1	22-12-2003
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		EP 0909234 A1	21-04-1999
DE 102006031273 A1	10-01-2008	NONE	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2011/003438

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☒ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-6

   Blood pump comprising a hub and a radially compressible and expandable rotor and a housing being expandable and compressible in radial direction, wherein a control body passes through said hub.

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2. claims: 7-15

   Blood pump comprising a housing and a drivable rotor being expandable and compressible, wherein said rotor and/or housing has selected regions of different material properties, and a method of producing said blood pump.
